Remarks

This is in response to the January 22, 2009 Office Action in the above-identified patent application.

I. Status of the Claims.

Original Claims 1-52 were pending for purposes of the instant Office Action. Claims 2, 5, and 48 have been canceled without prejudice. The remaining claims 1, 3-4, 6-47 and 49-52, as currently amended, are presented for reconsideration in the accompanying Listing of Claims, above.

Applicants appreciate the Examiner's careful consideration of the prior species election requirement, and its withdrawal in this Action.

It is respectfully submitted that no new matter was entered by the above amendments to the claims.

II. *Rejection under 35 USC §112*

Claims 1, 5-7, 12, 45, and 48 stand rejected under 35 USC §112, second paragraph as being indefinite. The Examiner has kindly pointed to the recitation in these rejected claims of a broad range or limitation together with a narrow range of limitation. Applicants respectfully traverse in view of the above amendments to the claims in this Reply.

Specifically, claims 1, 7, and 45 have been amended to remove the phrase "and preferably at least 70%" in each instance. Along with the cancellation of claims 5 and 48, the rejections as applied to these claims are now moot.

With regard to claim 6, applicants provide clarification which is believed to address the Examiner's concerns. Claim 1(a), as amended, now recites that the second segment is a "composition that lacks … drug or comprises at least a pharmacologically effective quantity of any drug" (emphasis supplied). The limitation in claim 1(a) no longer recites that the composition of the second segment "does not comprise a therapeutically effective quantity of a drug." Claim 6 then further limits this "pharmacologically effective" amount, defining it to be a therapeutically effective amount.

With regard to claim 12, which originally recited that the height of the third segment was greater than the combined height of the first and *third* segments, applicants have amended the claim to correct this typographical error. The claim now recites that the second segment has a height greater than the combined height of said first segment and said third segment.

In view of the above corrections and clarifications regarding the specific claim language, applicants respectfully request reconsideration and withdrawal of the rejections under 35 USC §112, second paragraph.

III. *Claim Objections under 37 CFR 1.75(c).*

Claim 2 is objected to as being of improper dependent form. Claim 2 is now canceled, as kindly suggested by the Examiner. Withdrawal of the objection to claim 2 is respectfully requested upon reconsideration.

IV. *Claim Rejections under 35 USC §103.*

Claims 1-11, 13-34, and 39-50 are rejected under 35 USC §103(a) as being unpatentable over Lieberman (Pharmaceutical Dosage Forms – tablets, 1990) in view of Geller (US Pat. No. 3,927,194). This rejection is respectfully traversed.

Under this rejection, the Examiner has first provided a reminder of the obligation under 37 CFR 1.56 to point out, in an application where joint inventors are named, the invention and invention dates of each claim that was not commonly owned at the time a later invention was made. Applicants are aware of the obligation, but are not aware of any claim in the subject application not commonly owned at the time of invention or of any later invention.

In making the rejection under 35 USC §103, the Office Action points out that Lieberman discloses layered tablets wherein the granulation layers are sandwiched on top of each other and the edges are exposed, and asserts that such disclosure reads on claim 25. The further disclosure in Lieberman of providing different coloring in the layers for unique identification is also cited as reading on claim 19. However, it should be noted that Lieberman summarizes the state of the art of tablet manufacture up to 1990 and does not contemplate the unique aspects of the layered, segmented tablets as currently claimed.

First, applicants respectfully direct the Examiner's attention to the claims as currently amended. Claim 1, as amended, recites in relevant portion the following:

A pharmaceutical dosage form comprising a pharmaceutical tablet comprising segments, in which a first segment comprises a composition comprising a pharmaceutical agent in a pharmacologically effective quantity, and a second segment comprising:

a) a substantially immediate release composition that lacks a pharmacologically effective quantity of any drug or comprises at least a pharmacologically effective quantity of any drug, said second segment forming

i) an outer segment that lacks a pharmacologically effective quantity of any drug adjacent to a segment comprising a pharmacologically effective quantity of any drug, or

ii) an inner segment that is adjacent above and below to segments that comprise a pharmacologically effective quantity of any drug wherein the drugs in the above and below segments are physically and chemically compatible with one another; or

b) optionally, a score greater than 50% through the maximum height of said scored segment; or

c) without limitation, a segment of said tablet in which said tablet has a height that is greater than any transverse dimension and

i) lacks a semi-permeable membrane coating, or

ii) lacks an osmotically active component to effect intrinsic altered release, or

iii) lacks a drug over-coating, or

iiii) said first and second segments contain pharmacologically effective quantity of any drug (...).

Thus, part (a)(i) of clam 1 is directed to a bi-layer tablet which contains an active segment and an immediate-release (IR) *inactive* segment. There is nothing in the prior art that describes this configuration because, previously, there was no need to include in a bi-layer tablet an IR inactive segment or layer in combination with the active segment or layer. The IR inactive layer is not intended to modify the release profile of the active segment and does not separate the active layer from another incompatible active layer. In the claimed invention, the inactive IR layer serves the unique purpose of providing a support layer so the active layer may be scored substantially through its entire thickness (or "height," as referred to in the subject application) without affecting the integrity of the tablet as a whole.

By contrast, the reference of Lieberman simply describes the state of the art at the time – i.e., the knowledge that providing, e.g., an IR *active* layer adjacent to a controlled-release *active* layer in a bi-layer tablet can be used to provide different release rates for each drug in the respective layers. Nowhere does Lieberman teach or suggest an *inactive* IR layer adjacent to an *active* layer in a bi-layer tablet.

Moreover, part (a)(ii) of claim 1 is directed to an embodiment of a tablet having three or more segments (layers). In this embodiment, the inner (second) segment is formed between ("above and below") two segments that are physically and chemically compatible with one another. There is nothing in Lieberman, or anywhere in the prior art to applicants' knowledge, that teaches or suggests adding a layer or segment between two compatible compositions. One reason for the lack of such teaching or suggestion in the prior art is because it was previously understood that providing an additional layer to separate two compatible compositions was superfluous, and could increase manufacturing time and costs.

As claimed, the subject invention provides an inner layer separating the two compatible compositions to allow division of the tablet by breaking through the inactive inner layer disposed between the compatible active layers. Providing the inner, inactive "breaking layer" advantageously allows breaking of the tablet through only that inactive layer, without damage to either of the adjacent active layers or segments. Such advantage was clearly not mentioned or contemplated by Lieberman.

Finally, part (c) of claim 1 is directed to tablet embodiments having their height greater than their width. The state of the art at the time of Lieberman did not envision tablets having this configuration. Accordingly, Lieberman cannot be said to teach or suggest a tablet as claimed in part (c) of claim 1.

Although the Office Action indicates that "Lieberman fails to directly envisage that the score on the multilayer tablet extends at least 70% of the distance of the first segment of said multilayer tablet", it is respectfully emphasized that Lieberman is further deficient in its teaching regarding each of the tablet embodiments described above, viz., (a) an inactive outer layer in a bi-layer IR tablet, (b) an inactive layer between two active layers which are compatible with one another, and (c) a tablet which has its height greater than its width.

These deficiencies of Lieberman are not cured by the addition of US Patent No. 3,927,194 to Geller. The Office Action apparently brings in Geller for its disclosure of scores up to 2/3 of the tablet thickness to reject claims 4, 8, 22, and 46-48 in combination with Lieberman. However, the Office Action admits that "Lieberman teaches … layered dosage forms [that] have the advantage of being able to separate two *incompatible* substances with an inert barrier or … [that] can be used *to modify the release profile*." See Office Action, at page 5 (emphasis supplied). The layers of the subject tablets are not provided to affect the release profile of the tablet or the individual layers; rather, the layers serve as either a support structure (of the bilayer tablet) or as a breaking region in the tablets having three or more layers.

There is no reason to modify Lieberman with the Geller score technique because Geller is concerned with making a single layer tablet with one active ingredient and does not suggest a two layered tablet. Also, neither Lieberman nor Geller, alone or in combination, suggest the concept of a tablet wherein all or most of the breakage occurs in an inert layer, which greatly increases the accuracy of the tablet splitting as compared to the accuracy of splitting a tablet by merely using a deep score through a homogeneous, non-layered tablet, as in Geller.

The different considerations that arise from such tablet breakage point to the unobviousness of the claimed invention as compared to the different concepts set forth in Lieberman and Geller. Each of the cited references describes tablet structures that are made for completely different purposes. The concept of the present invention is not found in either of the cited references.

Rejected claim 4 depends from claim 1 and, as stated above, is therefore directed to three different embodiments of tablets, none of which are taught or suggested by Lieberman, alone, or in combination with Geller. Specifically, claim 1 of the subject application claims (a) a bi-layer tablet having an inactive IR layer (thus no modification of release profile for each layer); (b) a tablet of three or more layers (segments) having an inner layer which separates *compatible* active compositions, or (c) a tablet having a height greater than its width. Thus, because Lieberman does not provide a teaching or suggestion of any one of these claimed embodiments, it cannot be used as a primary reference to support the combination with Geller in rejecting the subject claims.

Claim 8, similarly, is directed to embodiments not taught or suggested by Lieberman. Specifically, claim 8 is directed to embodiments that are either bilayer tablets, or are tablets that have three or more layers. The claimed bilayer tablet embodiments have either (a) an inactive layer, or (b) both layers containing the same drug (compatible compositions). Alternatively, the tablets of claim 8 that have three or more layers are directed to embodiments that include (c) a middle, separating layer between segments that contain the same drug or drugs (compatible compositions), (d) an inactive segment between two *compatible* compositions, or (e) an inactive middle segment which has "a height in excess of a minimum amount required to separate incompatible layers," i.e., a taller-than-wide tablet. As discussed above, Lieberman fails to disclose or suggest any one of these tablet configurations.

Claim 22 is directed to tablets having three or more layers wherein (a) each layer composition is compatible or (b) the tablet has its height greater than its width. Again, Lieberman fails to teach or suggest any one of these embodiments.

With regard to claims 46-48, it is noted that these claims depend from claim 45 – essentially directed to a bilayer tablet comprising (a) an inactive segment and a score that extends at least 50% through the tablet. Thus, the Office Action cites Geller as a secondary reference in combination with Lieberman to indicate that a score greater than 50% was known in the art. However, because Geller fails to cure the deficiencies of Lieberman, as detailed above, the depth of the score as described in Geller is inapposite to the claimed invention. Applicants therefore respectfully submit that the unique segmented tablets recited in the subject claims would not have been obvious over Lieberman, in view of Geller. Reconsideration and withdrawal of the rejection under 35 USC §103(a) is respectfully requested.

Claims 35-38 and 51-52 have also been rejected under 35 USC §103(a) as being unpatentable over Lieberman in view of Geller, and in view of Lofroth, et al., (US Pat. No. 6,827,947). The reference of Lofroth is cited for its description of coated tablets and sachets (claims 35 – 37) and for its disclosure of the treatment of certain medical conditions, including the use of metoprolol (claims 38 and 51-52). Applicants respectfully traverse in view of the amendments to the claims, and the remarks as set forth herein which establish that the claimed invention is neither taught or suggested from the primary reference of Lieberman, or the secondary reference of Geller.

The applicability of Lofroth is limited in that it used only to show disclosure of certain elements recited in these rejected dependent claims. Lofroth therefore clearly fails to cure the defects of

Lieberman and/or Geller, and thus, whether taken separately or together with those references, cannot further support an obviousness rejection of the independently claimed invention in the subject application. Accordingly, applicants respectfully submit that this rejection also fails, as the claimed invention would not have been obvious in view of any one of Lieberman, Geller, or Lofroth taken separately or together. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 35-38 and 51-52 under 35 USC §103(a).

Finally, claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/598,344. Because the instant claims have been amended, and the claims of either the instant application or the cited '344 application have not yet been allowed, applicants respectfully submit that the issue of obviousness-type double patenting, and the submission of a terminal disclaimer to overcome the obviousness-type double patenting rejection, will be considered upon indication of allowability for the claims.

In view of the above amendments to the claims and the accompanying Remarks, applicants believe that the pending claims, as amended, are in condition for allowance and respectfully request issuance of the Notice of Allowance forthwith.

Applicants invite the Examiner to contact the undersigned at the address and/or phone number provided below if clarification or additional information is needed on any of these matters.

Respectfully submitted,

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